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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,784	04/21/2006	Paul Adriaan Van Der Schaaf	LS/95-22963/A/PCT	5879

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CIBA SPECIALTY CHEMICALS CORPORATION  
PATENT DEPARTMENT  
540 WHITE PLAINS RD  
P O BOX 2005  
TARRYTOWN, NY 10591-9005

EXAMINER
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SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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10/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/576,784

Applicant(s)

VAN DER SCHAAF ET AL.

Examiner

Rei-tsang Shiao, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This application claims benefit of the foreign application:  
EUROPEAN PATENT OFFICE (EPO) 03103841.7 with a filing date 10/16/2003.
2. Applicant's remarks filed on August 06, 2007 is acknowledged. Claims 1-9 are pending in the application.

### ***Responses to Election/Restriction***

3. Claims 1-3 and 7 are prosecuted in the case. Claims 4-6 and 8-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

### ***Responses to Amendment/Arguments***

4. Applicants arguments regarding the rejection of claims 1-3 and 7 under 35 U.S.C., second paragraph filed on August 06, 2007, have been fully considered and they are not persuasive. It is unclear that the crystalline polymorphs of claims 1-3 are identical or different crystalline polymorphs. It is noted that the X-ray powder diffraction patterns of claims 1-3 share a number of common data, i.e., 10.1, 7.6 and 6.10. Moreover, there is only one crystalline polymorphs form (i.e., Form G) has been exemplified in the specification, see Fig. 1. Clarification is required.
5. Applicant's arguments regarding the rejection of claim 7 under 35 U.S.C. 112, first paragraph filed on August 06, 2007, have been fully considered and

they are not persuasive. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, the instant crystalline form, after mixing, grinding, compressing would be transformed into a thermodynamically stable form(s). Applicants are requested to disclose that the instant pharmaceutical composition comprising crystalline form is stable, and not changing to another form, e.g., Van Der Schaaf et al. '479 Form A, B1, B2, or C-E, after the processes of pharmaceutical preparation.

6. Applicant's arguments regarding the rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) filed on August 06, 2007, have been fully considered and they are not persuasive, in part. Since the instant X-ray powder diffraction patterns are distinct from Van Der Schaaf et al. Form A, B1, B2, or C-E, the rejection of claims 1-3 under 35 U.S.C. 102(b) has been withdrawn. However, Van Der Schaaf et al. discloses a pharmaceutical composition comprising the same instant compound fluvastatin sodium and a pharmaceutical acceptable diluent or carrier (i.e., aqueous solution). It is noted that an acceptable carrier can be water and therefore the instant crystal forms of the instant compound dissolves in the composition (i.e., aqueous solution), and it will exist in free form and not as a crystal form. Therefore the rejection of claim 7 under 35 U.S.C. 102(b) is maintained.

7. Applicant's arguments regarding the rejection of claims 1-3 and 7 under the obviousness-type double patenting over Van Der Schaaf et al. '643 or '479 filed on August 06, 2007, have been fully considered and they are not persuasive, in part. Since the instant X-ray powder diffraction patterns are distinct from Van Der Schaaf et

al. Form A, B1, B2, or C-E, the rejection of claims 1-3 under the obviousness-type double patenting has been withdrawn. However, Van Der Schaaf et al. claim a pharmaceutical composition comprising the same instant compound fluvastatin sodium and a pharmaceutical acceptable diluent or carrier (i.e., aqueous solution). It is noted that an acceptable carrier can be water and therefore the instant crystal forms of the instant compound dissolves in the composition (i.e., aqueous solution), and it will exist in free form and not as a crystal form. Therefore the rejection of claim 7 under the obviousness-type double patenting is maintained.

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Rei-tsang Shiao', with a stylized flourish at the end.

Rei-tsang Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

October 24, 2007